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DATE MAILED: 12/09/2010

NOTICE OF ALLOWANCE AND FEE(S) DUE

9629 7590 12/09/2010 MORGAN LEWIS & BOCKIUS LLP 1111 PENNSYLVANIA AVENUE NW WASHINGTON, DC 20004 EXAMINER
BETTON, TIMOTHY E

ART UNIT PAPER NUMBER

1607

 APPLICATION NO.
 FILING DATE
 FIRST NAMED INVENTOR
 ATTORNEY DOCKET NO.
 CONFERMATION NO.

 10/573,353
 06/08/2007
 Jay Lal Mehia
 056291-5246
 8786

TITLE OF INVENTION: THERAPEUTIC TREATMENT

| APPLN. TYPE | SMALL ENTITY | ISSUE FEE DUE | PUBLICATION FEE DUE | PREV. PAID ISSUE FEE | TOTAL FEE(S) DUE | DATE DUE |
|----------------|--------------|---------------|---------------------|----------------------|------------------|------------|
| nonprovisional | NO | \$1510 | \$300 | \$0 | \$1810 | 03/09/2011 |

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT, PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 1SI. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and I/2 the ISSUE FIEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

or <u>Fax</u> (571)-273-2885

| INSTRUCTIONS: This appropriate. All further indicated unless correcte maintenance fee notificat | form should be used f correspondence includir d below or directed oth ions. | or tran | smitting the ISSU Patent, advance or in Block 1, by (a | TE FEE and PUBLIC ders and notification a) specifying a new of | | | | | nould be completed where correspondence address as rate "FEE ADDRESS" for |
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| | 7590 12/09 WIS & BOCKIUS VANIA AVENUE , DC 20004 | S LLF | , | | | Cer | tificate | of Mailing or Trans | |
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| APPLICATION NO. | FILING DATE | | | FIRST NAMED INVEN | TOR | | ATTO | RNEY DOCKET NO. | CONFIRMATION NO. |
| 10/573,353 | 06/08/2007 | | | Jay Lal Mehta | | 0562 | | 056291-5246 | 8786 |
| TITLE OF INVENTION | THERAPEUTIC TREA | ATMEN | ŇΤ | • | | | | | |
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| APPLN. TYPE | SMALL ENTITY | ISS | SUE FEE DUE | PUBLICATION FEE I | OUE | PREV. PAID ISSU | SFEE | TOTAL FEE(S) DUE | DATE DUE |
| nonprovisional | NO | | \$1510 | \$300 | | \$0 | | \$1810 | 03/09/2011 |
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| BETTON, T | МОТНҮ Е | | I627 | 514-279000 | | • | | | |
| Change of corresponde CFR 1.363). | nce address or indicatio | n of "Fe | e Address" (37 | 2. For printing on | the p | atent front page, lis | t | | |
| | ondence address (or Cha 1/122) attached. | nge of | Correspondence | (I) the names of to or agents OR, alte | up to | 3 registered paten velv. | t attori | icys | |
| | | | | (2) the name of a | cinal | e firm (having as a | memb | era 2 | |
| PTO/SB/47; Rev 03-0 Number is required. | cation (or "Fee Address 2 or more recent) attach | ed. Use | of a Customer | 2 registered paten listed, no name wi | t atto | igent) and the nam rneys or agents. If printed. | no nan | ne is 3 | |
| 3. ASSIGNEE NAME A | | | | | | | | | |
| PLEASE NOTE: Unli recordation as set forth | ess an assignee is ident in 37 CFR 3.11. Comp | ified be detion o | low, no assignee of this form is NO | data will appear on t I a substitute for filin | the p | atent. If an assign assignment. | ee is io | lentified below, the do | cument has been filed for |
| (A) NAME OF ASSIC | | | | (B) RESIDENCE: (0 | | | | | |
| | | | | | | | | | |
| Please check the appropri | ate assignee category or | catego | ries (will not be pr | inted on the patent): | | Individual 🚨 Co | orporati | ion or other private gro | up entity Government |
| 4a. The following fee(s) | are submitted: | | 41 | | | se first reapply ar | ıy prev | lously paid issue fee | shown above) |
| Issue Fee | | | | A check is enclosed | | . F. DWG 2020 | | | |
| ☐ Publication Fee (No small entity discount permitted) ☐ Advance Order - # of Copies | | | ☐ Payment by credit card. Form PTO-2038 is attached. ☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any | | | | | | |
| | | | | overpayment, to | Depó | sit Account Numbe | er | (enclose a | extra copy of this form). |
| Change in Entity Stat Applicant claims | us (from status indicate SMALL ENTITY state | | | ☐ b. Applicant is no | o lon | ger claiming SMAI | LEN | ITTY status. See 37 CF | R 1.27(g)(2). |
| NOTE: The Issue Fee and interest as shown by the r | Publication Fee (if req ecords of the United Sta | uired) v tes Pate | vill not be accepted ent and Trademark | | | | | | e assignee or other party in |
| Authorized Signature | | | | | | Date | | | |
| Typed or printed name | | | | | | Registration N | lo | | |
| This collection of inform an application. Confident submitting the completed this form and/or suggesti Box 1450, Alexandria, V Alexandria, Virginia 223 | ation is required by 37 C iality is governed by 35 application form to the ons for reducing this bu- irginia 22313-1450. DC 13-1450. | FR 1.3 U.S.C. USPT USPT rden, sh | 11. The informatic 122 and 37 CFR O. Time will vary tould be sent to the SEND FEES OR 6 | on is required to obtain 1.14. This collection depending upon the e Chief Information C COMPLETED FORM | n or r is est indiv Office IS TO | etain a benefit by t imated to take 12 i idual case. Any co er, U.S. Patent and D'THIS ADDRESS | he pub minuter mment Trader | lic which is to file (and s to complete, includin is on the amount of tir nark Office, U.S. Depa D TO: Commissioner f | by the USPTO to process) g gathering, preparing, and ne you require to complete attment of Commerce, P.O. For Patents, P.O. Box 1450, |

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| 10/573,353 | 06/08/2007 | Jay Lal Mehta | 056291-5246 | 8786 | |
| 9629 7. | 590 12/09/2010 | EXAMINER | | | |
| MORGAN LEW | TS & BOCKIUS LLI | BETTON, TIMOTHY E | | | |
| | ANIA AVENUE NW | ART UNIT | PAPER NUMBER | | |
| WASHINGTON, | DC 20004 | | 1627 | | |

DATE MAILED: 12/09/2010

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Application No. Applicant(s) 10/573,353 MEHTA, JAY LAL Notice of Allowability Examiner Art Unit TIMOTHY E BETTON 1627 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308. This communication is responsive to 11/11/2010. 2. The allowed claim(s) is/are Claims 19 and 27-30 are found allowable. 3. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). b) \(\subseteq \text{Some* c} \) \(\subseteq \text{None of the:} \) a) \square All 1. T Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)). * Certified copies not received: _____. Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS NOT EXTENDABLE. 4. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient. CORRECTED DRAWINGS (as "replacement sheets") must be submitted. (a) Including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached 1) hereto or 2) to Paper No./Mail Date (b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d). 6. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL. Attachment(s) 1. | Notice of References Cited (PTO-892) 5. Notice of Informal Patent Application 2. Notice of Draftperson's Patent Drawing Review (PTO-948) Interview Summary (PTO-413), Paper No./Mail Date Information Disclosure Statements (PTO/SB/08). 7. ☐ Examiner's Amendment/Comment Paper No./Mail Date See Continuation Sheet 4. Examiner's Comment Regarding Requirement for Deposit 8. X Examiner's Statement of Reasons for Allowance of Biological Material 9. ☐ Other . TEB

Continuation Sheet (PTOL-37)

Application No. 10/573,353

Continuation of Attachment(s) 3. Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date: 2 pages, 3/24/2006; 2 pages, 6/22/2006; 7 pages, 6/8/2007; 1 page, 2/15/2008; 1 page, 10/30/2008; 1 page, 8/27/2009.

Application/Control Number: 10/573,353

Art Unit: 1627

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under Ex Parte Quayle, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114.

Applicant's submission filed on 11 November 2010 has been entered.

REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance: The prior art of record does not fairly teach a method of treating or reducing the extent of atherosclerosis comprising administering an effective amount of a combination consisting essentially of candesartan and rosuvastatin with an optional diuretic (HCTZ).

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance"

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIMOTHY E. BETTON whose telephone number is (571)272-9922. The examiner can normally be reached on Monday-Friday 8:30a - 5:00p.

Art Unit: 1627

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TEB

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1627